Method and device for ultrasound measurement of blood flow

The present invention relates to a method for ultrasound measurement in accordance with the preamble of claim 1 and to a device for ultrasound measurement in accordance with the preamble of claim 21.

In particular, the present invention relates to the ultrasound measurement of the blood flow in the human or animal body through a dynamic or irregular orifice, for example an insufficient or stenosed heart valve, a constricted vein or artery or similar. It is desirable, for example, to determine the cross-sectional surface area of flow, hereinafter shortened to (effective) opening surface area, the volumetric flow rate and/or the flow volume in a diseased heart valve, in particular the return flow through a diseased heart valve, in order thereby to be able to determine the severity of a valve defect and, if appropriate, perform a heart valve operation with optimum results.

WO 00/51495 A1, which forms the starting point of the present invention, discloses an ultrasound measurement method in which pulsed ultrasound signals are emitted and the backscattered ultrasound signals are evaluated on the basis of the Doppler technique.

For example, in the case of an insufficient heart valve, in order to determine the opening surface area, the volumetric flow rate, the flow volume and/or a value proportional thereto (hereinafter also shortened to measurement values) of the blood return flow, the measurement area of a reference beam must lie within the vena contracta (beam constriction) in the return flow of the blood through the heart valve, and the measurement area of a measurement beam must completely cover the vena contracta of the return flow through the insufficient heart valve. The positioning of the measurement areas has hitherto only been possible manually, and it requires great manual dexterity and considerable experience on the part of the operator. Moreover, a problem of the known method is that the orifice of an insufficient heart valve can be several centimetres at its maximum extent and for this reason the orifice can no longer be completely covered by the measurement area of a conventional measurement beam.

US 6,464,642 B1 discloses a two-dimensional, so-called multi-array transducer for ultrasonic diagnostic in general, wherein a three-dimensional region of interest, e.g. the heart of a patient, can be displayed and Doppler signals evaluated.

In the present invention, a spatial area/volume is sonified, i.e. exposed to ultrasound, by a transmit beam. The backscatter of different sample volumes of this sonified volume is detected and evaluated, wherein the sample volumes are located at least essentially in a common plane and have different cross sections transversal to beam direction, but at least essentially the same extension in beam direction. In the present invention, the term "measurement area" designates the sample volume with the respective cross section transversal to beam direction. The backscattered ultrasound waves are called "measurement beam" and "reference beam", wherein the measurement beam has a greater measurement area than the reference beam. Preferably, the measurement area of the reference beam lies within the measurement area of the measurement beam. Thus, the terms "measurement beam" and "reference beam" designate in particular Doppler signals backscattered from the respective measurement area.

The object of the present invention is to provide a method and a device for ultrasound measurement of at least one of the opening surface area of a dynamic or irregular orifice through which a fluid flows, in particular blood, of the volumetric flow rate, and of flow volume through the orifice, permitting simple and preferably automated operation and/or an accurate measurement, in particular on a relatively large or irregularly shaped or dynamic orifice.

The above object is achieved by a method according to claim 1 or 13 or a device according to claim 21. Advantageous embodiments are subject of the subclaims.

According to one aspect of the present invention, the measurement area of the measurement beam, particularly within the heart, is moved three-dimensionally beforehand in a search mode, in particular by means of a suitably controlled matrix array transducer, while Doppler signals are continuously detected and are evaluated in respect of the occurrence of a Doppler spectrum characteristic of a vena contracta. For example, the measurement area is moved in a meandering configuration and in different planes in succession, in order to locate a spatial region in which there is a vena contracta of the fluid flowing through an orifice.

This greatly facilitates the practical application of the measurement method and the operation of a measurement device. In particular, automated detection of a vena contracta is possible without the operator requiring great experience or manual dexterity.

According to a further aspect of the present invention, and one which can also be realized independently, several measurement beams with offset spatial, partially overlapping measurement areas covering the orifice completely, and/or several reference beams with offset spatial measurement areas are evaluated for determination of the measurement values. This leads to several advantages.

The detection and evaluation of several offset measurement areas (these can optionally be the measurement areas of several measurement beams and/or of several reference beams) permit fine adjustment and, if appropriate, correction of motion or location during the measurement, so that it is possible to achieve a reliable complete coverage of the orifice by the measurement beams and/or a reliable positioning of a measurement area of a reference beam in the inside of the vena contracta of the fluid flowing through the orifice.

The mutually overlapping measurement areas of the measurement beams permit a reliable coverage of larger orifices too, so that improved and more accurate determination of the measurement values is made possible.

In particular, it is proposed to use what is called a matrix array transducer to generate preferably only one transmit beam to sonify a broad volume and to detect, preferably simultaneously if possible or sequentially, the measurement beams of different broad measurement areas and preferably the reference beams of different narrow measurement areas. This permits a simple, versatile structure, in which the directions of the beams and the depth range evaluated, and consequently the position of the measurement areas, can be controlled, in particular moved and adapted, electronically.

Further advantages, features, properties and aspects of the present invention will become evident from the following description of a preferred illustrative embodiment with reference to the drawing, in which:

Fig. 1 shows a diagrammatic illustration of a proposed device for ultrasound measurement of the return flow through an insufficient heart valve;

Fig. 2 shows a diagrammatic illustration of a transmit beam in ultrasound measurement of a vena contracta in an orifice;

Fig. 3 shows a diagrammatic illustration of a measurement beam and of a reference beam in ultrasound measurement of a vena contracta in the orifice;

Fig. 4 shows a Doppler spectrum of a vena contracta;

Fig. 5 shows a diagrammatic illustration of the device and method in a search mode;

Fig. 6 shows a diagrammatic illustration of an insufficient heart valve and different positions of the measurement areas of the measurement beam and of reference beam in the ultrasound measurement; and

Fig. 7 shows a display unit of the device.

The diagrammatic illustration in Fig. 1 shows a proposed device 1 and a proposed method for ultrasound measurement of the opening surface area of a dynamic and/or irregular orifice 2 through which a fluid flows, in particular blood 3, and/or of the volumetric flow rate and/or flow volume through the orifice 2.

In the diagrammatic illustration in Fig. 1, only part of a body 4 is indicated, with a heart 5 which is to be examined and through which blood 3 flows. A heart valve, in this case the mitral valve 15, is insufficient and therefore does not close completely during the contraction of the ventricles (hereinafter called systole), but instead forms the orifice 2 indicated diagrammatically in Fig. 1. During the systole, blood 3 flows back through the orifice 2.

By means of the proposed device 1 and the proposed method, it is possible to determine "measurement values", namely the effective opening surface area (for example a mean value, or the profile varying during the measurement or flow pe-

riod) of the orifice 2, the volumetric flow rate of blood 3, in particular of the returning blood 3, which varies over time during the measurement or flow period, the total flow volume of the (returning) blood 3, and/or a proportional value.

However, the proposed method is not limited to determining the measurement values in a mitral valve, and instead can be used to determine the measurement values in any heart valve or in any other dynamic and/or irregular orifice 2, particularly one through which blood 3 flows, for example a hole in the cardiac septum, a stenosed vein or artery, or similar. Moreover, the proposed method is not limited to determining the measurement values in a single orifice 2, and instead can also determine the measurement values of several orifices 2 in succession (for example during systole in an insufficient mitral valve and during diastole (relaxation and filling of the ventricles) in an insufficient aortic valve) or simultaneously (for example in the case of two orifices 2 in an insufficient mitral valve or in an insufficient mitral valve and a stenosed aortic valve).

Figures 2 and 3 illustrate the basic principle of ultrasound measurement. A fluid, such as blood 3, flows through the diagrammatically indicated orifice 2, and forms adjacent to the orifice 2 in a region 6 a flow constriction with at least substantially laminar flow that is therefore also designated as vena contracta. Depending on several factors, as the shape of the orifice 2 and the blood 3, this laminar flow region 6 further narrows and merges increasingly into a turbulent current, as indicated diagrammatically in Figures 2 and 3.

In particular, the proposed method relates to locating and/or measuring a vena contracta with a flow constriction of factor 0.65 to 0.85 (surface area or diameter of the narrowed area 6 to surface area or diameter of the orifice 2).

Pulsed ultrasound signals are emitted in an ultrasound beam (transmit beam), as is indicated in Fig. 2, and the backscatter of ultrasound Doppler signals of a measurement beam 7 and of a reference beam 8 for determination of the measurement values is detected and evaluated, as is indicated in Fig. 3. The measurement beam 7 has a larger or wider measurement area 9. By contrast, the reference beam 8 has a smaller or narrower measurement area 10, which preferably lies centrally within the measurement area 9.

To generate and to receive or detect the ultrasound waves, a multi-array transducer 11 is preferably used. The transducer 11 has a multiplicity of ultrasound generators, for example piezo elements, which are arranged in particular in a matrix formation and whose phase and amplitude can be controlled in such a way that the ultrasound waves are emitted as transmit beam 12, as indicated in Fig. 2, and the direction of the transmit beam 12 and its width or cross section can be controlled electronically.

Accordingly, a spatial area/volume is sonified by the transmit beam 12. The measurement areas 9, 10 relate to different sample volumes of this sonified volume that are located at least essentially in a common plane and have different cross sections transversal to beam direction and that backscatter the measurement beam 7 and the reference beam 8, respectively.

As regards the transducer 11 and the behaviour of the ultrasound waves, it should be noted that ultrasound generation across a large surface area (aperture) on the transducer 11 results in a converging transmit beam 12, that is to say a transmit beam which is relatively narrow or thin in the target area. By contrast, a relatively wide transmit beam 12, that is to say a transmit beam 12 which is of greater cross section or less convergent, shown diverging in Fig. 2 for illustration, is obtained when the ultrasound waves are emitted only from a small transducer area or aperture, that is to say when ultrasound waves are emitted by only a relatively small number of ultrasound generators, for example those lying at the centre of the transducer 11.

The ultrasound waves also show the aforementioned behaviour when received. The size of the measurement area 9, 10 can be controlled by suitable choice of the receiving transducer aperture or area and evaluation. Fig. 3 shows that, with a small receiving transducer aperture or area, that is to say activation and evaluation of only some of the ultrasound generators/ultrasound receivers or piezo elements of the transducer 11, the received measurement beam 7 has a relatively wide measurement area 9, i.e. of large cross section. Conversely, the reference beam 8 has a narrow measurement area 10, i.e. of small cross section, with a large receiving transducer aperture or area, that is to say activation of many or all of the ultrasound generators/ultrasound receivers or piezo elements of the transducer 11.

The transducer 11 generates the transmit beam 12 and receives the measurement beam 7 and the reference beam 8 in brief succession and iteratively one after another, and in this connection it is preferable for only a wide transmit beam 12 to be generated which insonates both measurement areas 9 and 10 at the same time, so that the measurement beam 7 and the reference beam 8 can be detected and evaluated simultaneously, with on the one hand only a small receiving transducer aperture of the transducer 11 being evaluated and on the other hand a large receiving transducer aperture of the transducer 11 being evaluated, this preferably being done by parallel data processing at sufficient speed and simultaneously.

In particular, through the emission of pulsed ultrasound signals and the Doppler effect, it is possible to determine and fix the position and depth of the measurement areas 9, 10.

Therefore, by means of the multi-array transducer 11 preferably provided, or by means of any other suitable sound generator and receiver, both the spatial position and also the size (in particular the cross section and depth) of the measurement areas 9, 10 can be controlled or fixed by appropriate evaluation in the proposed ultrasound measurement method.

To perform the ultrasound measurements and to control the transducer 11, the device 1 preferably comprises, in addition to the transducer 11 itself, a control unit 13 and an associated display unit 14, as indicated in Fig. 1.

The power and velocity spectra of the Doppler signals and of the measurement beam 7 and reference beam 8 are detected and evaluated in particular.

Fig. 4 shows by way of example a diagrammatic Doppler spectrum (velocity as a function of time) of a vena contracta in a mitral valve, i.e. the return flow of blood 3 during two consecutive systoles. The Doppler spectrum does not in fact show a sharply contoured curve, but instead, per time, a spectrum of Doppler signals with different velocities and a spectrum of different backscattering power which varies with the partial measurement areas of different velocity, as is indicated by the dotted area in Fig. 4.

The integral of the power values over velocity or the velocity spectrum at a given time represents a measure of the opening surface area of the orifice 2 if the measurement area 9 completely encloses or covers the orifice 2. The reference beam 8 is chosen so that its measurement area 10 lies completely within the vena contracta, wherein the area (cross section) of the measurement area 10 is known or can be calculated.

By means of the reference beam 8, it is then possible, by suitable integral formation, to determine a calibration coefficient of the power backscattered from measurement area 10. This calibration coefficient, the known area (cross section) of the measurement area 10, and the power integral value obtained from the measurement beam 7 are used to determine the absolute value of the effective opening surface area of the orifice 2.

The effective opening surface area is the cross sectional area of flow actually acting in the vena contracta and is smaller by the factor 0.65-0.85 than the geometric opening surface area. The effective opening surface area is simply called "opening surface area" hereinafter and in the claims.

Accordingly, by integration of the product of power and velocity over the velocity or the velocity spectrum, it is possible to determine the absolute volumetric flow rate and, with additional integration over time, the absolute flow volume.

Thus, the measurement values can be obtained. Further details, in particular concerning the aforementioned measurement and determination of the measurement values or other aspects of the measurement, are set out in WO 00/51495 A1, which is herewith incorporated in its full scope as supplementary disclosure.

Fig. 5 shows a diagrammatic illustration of the proposed device 1 and the proposed method in a search mode. Here, preferably only the wide transmit beam 12 and wide measurement beam 7 are used. The detection and evaluation of the reference beam 8 may, if necessary, be omitted in the search mode with a view to rapid processing.

The transmit beam 12 (not shown in Figure 5) and the indicated measurement beam 7 are preferably moved in a meandering pattern, through corresponding

control of the transducer 11, in order to scan or travel through the entire heart 5, e.g. as shown in Fig. 5 with broken lines in a pyramid shape, or through a partial volume of interest, e.g. one defined by an operator. Here, by means of suitable evaluation, the measurement area 9 of the measurement beam 7 is also positioned along the measurement beam 7 at different locations, so that, in view of the movement of the measurement beam 7, the measurement area 9 is moved in three dimensions, while Doppler signals are continuously detected and are evaluated in respect of the occurrence of a Doppler spectrum characteristic of a vena contracta.

The scanning or search process can take place quasi continuously or steplessly on account of the rapid data processing and short operating times. However, a large number of measurements are in fact carried out iteratively in succession, the position of the detected and evaluated measurement area 9 being changed in incremental stages in order to scan the whole of the possible or the intended volume for occurrence of a Doppler spectrum characteristic of a vena contracta. It also becomes clear that, from this systematic scanning a three-dimensional data set (volume) with the information of the spatial distribution of velocity and volume flow can be obtained and that this data set can be used later after the scanning has been completed to determine the occurrence of a vena contracta or even the measurement values of the vena contracta.

From what has been stated above, it will be clear that the proposed transducer 11 is preferably constructed in such a way that the ultrasound beams 7, 8, 12 can be moved in, for example, a conical spatial area with great spatial angle or cone angle. Accordingly, the transducer 11 is preferably what is called a two-dimensional matrix-array transducer, in other words an arrangement of ultrasound generators/ultrasound receivers or piezo elements which covers a large transducer aperture or area and extends in both area or aperture dimensions.

To determine whether there is a Doppler spectrum which is characteristic of a vena contracta, a filtering process is preferably carried out first. For example, all velocity values below a minimum limit V_{MIN} of, for example, 100 cm/s are not taken into consideration and/or only velocity values are considered which show a bell-shaped or approximately normal-distribution velocity profile and/or lie above a minimum value of, for example, 20-50% of the maximum value of the

respective spectrum. Thereafter, for the spectra or values preferably filtered or prepared in some other suitable way, a check is preferably made to ascertain

whether the mean velocity exceeds a minimum value, or the mean velocity of a selected spectrum or measurement area 9 is maximal for all spectra and/or measurement areas 9,

whether the width of the Doppler or velocity spectrum falls below a maximum value, or the width of a selected Doppler or velocity spectrum is minimal for all spectra and/or measurement areas 9,

whether the power or the power integral over the velocity spectrum exceeds a minimum value, or the power or the power integral over a selected spectrum is maximal for all spectra and/or measurement areas 9,

whether the Doppler spectrum shows an at least substantially continuous or constant line of maximal velocity, as is indicated in Fig. 4, and/or

whether the velocity spectrum at a given time, in particular at maximum velocity, as is indicated in Fig. 4, shows at least substantially a Gaussian distribution or normal distribution.

It is only when at least one, two or preferably all of the aforementioned conditions are satisfied that the occurrence of a vena contracta is established or at least provisionally assumed, or displayed to an operator for selection, by the proposed method and proposed device 1, it being possible, if necessary, to switch to an imaging mode which depicts the spatial location of the suspected vena contracta.

After the occurrence of a vena contracta has been established, it is possible, either automatically or in response to a corresponding confirmation signal from an operator, to direct the measurement area 9, 10 of the measurement beam 7 and the reference beam 8 to the suspected vena contracta and then perform an ultrasound measurement to determine the measurement values, as already explained above or in particular as described in more detail below. The proposed device 1 and the proposed method thus permit automated navigation to, location, and measurement of a dynamic and/or irregular orifice 2 through which a fluid flows, such as blood 3, and/or of the volumetric flow rate and/or flow volume through the orifice 2.

A preferred approach in the actual measurement or determination of the measurement values is explained below with reference to Fig. 6. Fig. 6 shows a diagrammatic illustration of an insufficient heart valve, in particular a mitral valve 15 which does not properly close during systole and accordingly presents the orifice 2. The orifice 2 can have a considerable size, in particular a length of several centimetres.

As indicated in Fig. 6, the maximum extent of the orifice 2 can be greater than the area that can be covered by the measurement area 9 of one measurement beam 7. In this connection, it should be borne in mind that the measurement area 9 cannot be arbitrarily enlarged, since the power or power density both of the transmit beam 12 and also of the measurement beam 7 decreases as the size or cross-sectional area increases; for an accurate measurement, however, a certain power or a certain signal-to-noise ratio is necessary in the signals that can be evaluated.

The proposed method and device 1 are preferably characterized by the fact that several measurement beams 7 with offset spatial, partially overlapping measurement areas 9 are detected and evaluated for determination of the measurement values. These measurement areas 9 are arranged, located and, if necessary, corrected to that the overlapping measurement areas 9 cover the orifice 2 completely, at least during the measurement.

In particular, a central measurement beam 7 with central measurement area 9 is surrounded, in a rosette formation, by the further measurement beams 7 with their measurement areas 9, as can be seen from the measurement areas 9 shown in Fig. 6. However, other configuration, e.g. two or more lines with offset measurement areas 9, can be provided, wherein the measurement areas 9 overlap in a similar manner.

Several measurement beams 7 with measurement areas 9, in particular all measurement beams 7 with measurement areas 9, are preferably detected and evaluated simultaneously or in succession iteratively within a measurement or measurement period. All measurement areas 9 are preferably evaluated cumulatively, it being possible for their overlaps areas 9 to be compensated, if necessary, so

that it is possible to achieve a homogeneous power distribution which is as uniform as possible over the area formed by all the individual measurement areas 9.

The preferably peripheral superposition or any other suitable superposition of the measurement areas 9 has the result that the orifice 2 is covered completely by the measurement areas 9 and, accordingly, an accurate determination of the measurement values can be guaranteed.

Each measurement beam 7 is preferably assigned a reference beam 8, as indicated in Fig. 6 by the measurement areas 10 of reference beams 8 assigned to the measurement areas 9 of the measurement beams 7. In particular, the detection and evaluation for each measurement beam 7 and the reference beam 8 assigned to it take place simultaneously.

All the reference beams 8 are preferably detected and evaluated in succession iteratively within a measurement or measurement period.

The several offset measurement areas 9 of the measurement beams 7 permit fine adjustment and correction during the measurement period. If the power integral of the central measurement beam 7 or another measurement value no longer shows the highest value in relation to another measurement beam 7 with laterally offset measurement area 9, the measurement areas 9, 10 are corrected in such a way that the central measurement beam 7 with its measurement area 9 lies again in the centre of the orifice 2. This adjustment or correction is important in particular when the spatial position of orifice 2 is dynamic, that is to say changes during a measurement period, in particular moves laterally and/or when the position of the transducer 11 in relation to the vena contracta changes.

Alternatively or in addition, the aforementioned fine adjustment or correction can also be effected by evaluation of the values provided by the reference beams 8 or of values proportional thereto, the position of the central reference beam 8 with its measurement area 10 being continuously corrected particularly in such a way that the central measurement area 10, during the entire measurement period, preferably remains completely within the vena contracta.

To evaluate the reference beams 8, it should further be noted that a reference beam 8 is chosen to form a calibration coefficient for all the measurement beams 7, and in particular the highest calibration coefficient of all the reference beams 8 can be used as calibration coefficient for all the measurement beams 7.

The calibration coefficient of the reference beams 8 are preferably also continuously determined, and the position of the measurement areas 9, 10 is corrected, as a function of the calibration coefficient during a measurement period, particularly in such a way that the measurement areas 9, 10 are displaced in parallel into the direction from the central measurement area 9, 10 to where a higher calibration coefficient has occurred.

In the evaluation of the measurement beams 7 and reference beams 8 and determination of the measurement values, it is possible, if necessary, to ignore those backscatters or measurement beams 7 and reference beams 8 for which a correct position of the measurement areas 9, 10 was not present or not guaranteed, for example if the abovementioned criteria for the presence of a Doppler spectrum characterizing a vena contracta were not satisfied.

According to a further embodiment, the proposed method and the proposed device 1 are characterized by the fact that the measurement values for several separate orifices 2 can be determined either in succession or simultaneously during a measurement period. Thus, it is possible, for example, that two separate orifices 2, with in each case a Doppler spectrum characterizing a vena contracta, are detected in the search mode and are thereafter measured either in succession or simultaneously to determine the measurement values. The measurement values can then be displayed to the operator, for example by means of the display unit 14 shown diagrammatically in Fig. 7. Depending on the temporary status (systole or diastole) and the flow (positive or negative), it will be evident to the trained operator what type of heart valve and disease are involved, for example an insufficient mitral valve in the display shown, where positive speeds denote flow in the direction towards the transducer 11 and negative speeds denote flow in the direction away from the transducer 11.

The proposed device 1 and the proposed method are universally applicable, and the proposed automation in particular permits simple and safe operation and a rapid examination or measurement.

Preferably, the transducer 11 is not held manually by an operator, but fixed by means of a suitable support not shown or the like, in particular on the breast of a patient not shown.